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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,672	12/09/2003	Shulamit Levenberg	0492611-0530/MIT-10077	6356

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EXAMINER	
SGAGIAS, MAGDALENE K	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,672	LEVENBERG ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) *59-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-70 are pending.

Election/Restrictions

Applicant's election with traverse of group I, claims 1-58 in the reply filed on 07/24/06 is acknowledged. The traversal is on the ground(s) that the growth factors recited in claims 21 and 46 are species of the invention as recited in claims 20 and 45, that they fall under the same patent classification and that they can be searched together. This is not found persuasive because each growth factor has distinct structure and function and have distinct effects on the growth and differentiation of cells hence they require separate search in patent and non-patent literature so that a search of one growth factor is not co-extensive. For example, a search of cytokines, for a tissue-engineering construct, will not provide a search on eicosanoids of identifying growth differentiation factors for a tissue-engineering construct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 59-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/24/06.

Claims 1-58 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-15 are rejected under 35 U.S.C. 102(a) as being anticipated by **Levenberg et al,** (PNAS, 99(7): 4391-4396, 2002).

Levenberg teaches a tissue-engineering construct, comprising human embryonic stem cells, a three-dimensional cell support matrix wherein cells exposed to endothelial growth medium EGM-2 which contains growth factors cytokines and supplements and wherein embryonic stem cells differentiate into vascular-like structures (abstract, p 4393). **Levenberg** also teaches a tissue engineered construct wherein the cell support matrix comprises poly-(L-lactic acid) (PLLA) and poly lactic-glycolic acid (PLGA) mixed 1:1 (p 4392, 2nd column). **Levenberg** also teaches the cell support matrix is biodegradable (p 4392, 2nd column). **Levenberg** also teaches the cells were mixed 1:1 mix of culture medium and matrigel polymer sponges (p 4392, 2nd column).

Further, the tissue engineered construct of **Levenberg** would inherently be resistant to contractile forces exerted by the stem cells. A product and its properties cannot be separated. As the three dimensional matrix of **Levenberg** cannot be distinguished from those claimed, the properties of the tissue engineering construct of **Levenberg** and those claimed would have the same properties. Thus, **Levenberg** et al, clearly anticipates the instant invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the

burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Applicant is referred to MPEP 2112.

Thus, **Levenberg** et al, clearly anticipates the claimed invention.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by **Buttery et al,** (Tissue Eng, 7(1): 89-99, 2001).

Buttery et al, teaches a tissue engineering construct comprising of pluripotent murine embryonic stem cells within an extracellular matrix of collagen-1 and osteocalcin and the

differentiation of embryonic stem cells into osteoblasts by supplementing the serum-containing media with ascorbic acid, beta-glycerophosphate and/or dexamethasone/retinoic acid or by co-culture with murine osteoblasts (abstract).

Further, the tissue engineered construct of **Buttery** would inherently be resistant to contractile forces exerted by the stem cells. A product and its properties cannot be separated. As the three dimensional matrix of **Buttery** cannot be distinguished from those claimed, the properties of the tissue engineering construct of **Buttery** and those claimed would have the same properties. Thus, **Buttery** et al, clearly anticipates the instant invention.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown

property, which is inherently present in the prior art, does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Applicant is referred to MPEP 2112.

Thus, **Buttery** et al, clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-51, 54-55, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Naughton et al,** (US 5,962,325) in view of **Griffith et al,** (Science, 295: 1009-1014, 2002).

Naughton et al, teaches a method of stimulating the proliferation and appropriate cell maturation of a variety of different cells and tissues in three-dimensional cell support cultures in vitro using TGF-β in culture medium (abstract). Naughton teaches examples wherein chondrocytes from articular cartilage of New Zealand rabbits or cows were grown in culture monolayer or on three-dimensional biodegradable, biocompatible fibrous framework or scaffold formed of sterilized polymers such as polyglycolic acid, polylactic acid or other polymers (column 7, lines 24-29). Naughton teaches that chondrocyte progenitors may be obtained from umbilical cord or placenta tissue or umbilical cord blood (column 11, lines 60-65). Naughton

also teaches exogenous TGF-β_1 was added to the three-dimensional cultures to achieve a greatly increased proliferation and differentiation of chondrocyte cells (column 7, lines 24-40). Naughton teaches a method of promoting cartilage tissue development comprising providing a population of rabbit chondrocytes after exposing the cells to TGF-β_1 (column 20, 26). Naughton further teaches a living stromal tissue prepared in vitro, comprising mesenchymal stem cells and connective tissue proteins naturally secreted by the mesenchymal stem cells attached to and substantially enveloping a three-dimensional framework composed of a biocompatible, non-living material formed into a three-dimensional structure having interstitial spaces bridges by the mesenchymal stem cells (column 26). Naughton also teaches that the stem cells for the inoculation into the three-dimensional tissue construct may be obtained from human patients (column 9). **Naughton** also teaches that the resulting three-dimensional cultures and biological replacement tissue constructs have a variety of applications ranging from transplantation to implantation in vivo (abstract). **Naughton** differs from the claimed invention by not teaching a method for producing a tissue engineering construct, comprising providing a population of embryonic stem cells differentiating into cartilaginous tissue.

However at the time of the instant invention **Griffith et al,** (Science, 295: 1009-1014, 2002) teaches three-dimensional scaffolds that are suitable for growing composite tissue structures such as bone (p 1012, figure 1). Griffith et al, also teaches that there are three principal therapeutic strategies for treating diseased or injured tissues in patients: (i) implantation of freshly isolated cells or cultured cells (ii) implantation of tissues assembled in vitro from cells and scaffolds and (iii) in situ tissue regeneration (p 1009, 2nd and 3rd column). Griffith et al, also teaches that each category may be further delineated in terms whether the cells are adult or embryonic stem cells (p 1009, 3rd column). Further, Griffith et al, suggests that given the donor and patient cells are already being exploited therapeutically, embryonic stem

cells hold great promise for treating damaged tissue where the source of cells for repair is **extremely limited or not readily accessible** (p 1010, 1st column last paragraph). Griffith et al, went on to say that embryonic stem cells are attractive because they can be expanded in an undifferentiated state in vitro and can be induced to form many different cell types (p 1010, 1st column and 2nd column). Griffith et al, also teaches that the scaffolds are porous, degradable structures fabricated from either natural materials such as collagen, fibrin or synthetic polymers such as polyglycolide, polylactide, polylactide coglycolide and they can be spongelike sheets, gels of highly complex structures with intricate pores and channels fabricated using new material-processing technologies (p 1010, 3rd column). Griffith et al, also teaches scaffolds can be also designed to release growth factors that induce cellular differentiation and tissue growth in vitro, or cell migration into the wound site in vivo (p 1012, 1st column) and presenting growth factors as part of an extracellular matrix, rather than just releasing them into the liquid medium has improved nerve regeneration (p 1012, 3rd column). Griffith et al, also teaches the three dimensional cell support matrix for in vivo bone scaffolds coated with adhesion proteins such as fibronectin and other extracellular matrix glycoproteins containing the amino acid sequence Arg-Gly-Asp (RGD) morif promote maximal tissue in growth only at intermediate values of ligand surface density, likewise, only at an intermediate density do adhesion proteins on scaffolds induce neuro progenitor cells to extend to neuritis, a prerequisite for nerve regeneration (p 1012, 2nd column). Griffith et al, suggests that using gel scaffolds that incorporate a complete compendium of growth factors and their correctly presented adhesion sites may be the next step in tissue engineering. As such **Griffith et al,** provide sufficient motivation for one of ordinary skill in the art to apply the in three-dimensional cell support cultures in vitro using TGF-β in culture medium of **Naughton** using embryonic stem cells under growth conditions as suggested by Griffith for the production cartilaginous tissue.

Accordingly, in view of the teachings of **Griffith et al,** it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the tissue engineered construct of **Naughton** by use of embryonic stem cells with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as Griffith suggested engineered tissues could reduce the need for organ replacement, and could greatly accelerate the development of new drugs that may cure patients eliminating the need for organ transplants altogether and in particular embryonic stem cells hold great promise for treating damaged tissue where the source of cells for repair is extremely limited or not readily accessible.

Thus, the claimed invention as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

Claims 53-54, 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Levenberg et al,** (PNAS, 99(7): 4391-4396, 2002) in view of **Guan et al,** (Cell Tissue Res, 305: 171-176, 2001.

Levenberg et al, (PNAS, 99(7): 4391-4396, 2002) teach human embryonic stem cells have the potential to differentiate into various cell types and thus may be useful as a source of cells for transplantation or tissue engineering and teaches a three-dimensional polymer matrix composed of poly-(L-lacticacid) (PLLA) and polylactic-glycolic acid (PLGA) mixed 1:1 (p 4392, 2nd column). **Levenberg** teaches the differentiation of human embryonic stem cells into endothelial cells forming vascular-like structures (abstract and p 4393 and figure 2). **Levenberg** also suggests that efforts to identify and isolate early embryonic cell progenitors are important to provide tools for elucidating regulatory elements in vasculogenesis and to potentially shed light on vasculogenic and angiogenic mechanisms involved in pathological situations affecting the

vascular system (p 4396, 2nd paragraph). **Levenberg** also teaches that unlike the mouse system the lack of experimental cell systems has made it difficult to study developmental processes in the human (p 4391, 1st column) and suggests it would be important to examine the efficiency of embryonic stem cell differentiation into endothelial cells in applications such as tissue engineering of vascular grafts (p 4396, 1st column). **Levenberg** differs from the claimed invention for not teaching exposing the embryonic stem cells to retinoic acid, wherein the cells develop neuronal structures.

However at the time of the claimed invention was made, **Guan** teaches differentiation of murine embryonic stem cells into neuronal cells by using high levels of retinoic acid (p 172 and figure 1). **Guan** also suggests that by directing embryonic stem cells along particular pathways of neuronal differentiation, homogeneous cell populations may be generated as neuronal grafts for cell transplantation (p 175, 2nd column). As such, Guan provides sufficient motivation for one of ordinary skill in the art to apply the three-dimensional cell support system of **Levenberg** using human embryonic stem cells to differentiate into neuronal structures after exposure into retinoic acid.

Accordingly, in view of the teachings of **Guan,** it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the tissue engineered construct of **Levenberg** by use of retinoic acid with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as **Guan** suggested that by directing embryonic stem cells along particular pathways of neuronal differentiation, homogeneous cell populations might be generated as neuronal grafts for cell transplantation.

Thus, the claimed invention as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

Claims 52-54, 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Levenberg et al,** (PNAS, 99(7): 4391-4396, 2002) in view of **Benvenisty et al,** (US 2002/0146678).

Levenberg et al, (PNAS, 99(7): 4391-4396, 2002) teach human embryonic stem cells have the potential to differentiate into various cell types and thus may be useful as a source of cells for transplantation or tissue engineering and teaches a three-dimensional polymer matrix composed of poly-(L-lacticacid) (PLLA) and polylactic-glycolic acid (PLGA) mixed 1:1 (p 4392, 2nd column). **Levenberg** teaches the differentiation of human embryonic stem cells into endothelial cells forming vascular-like structures (abstract and p 4393 and figure 2). **Levenberg** also suggests that efforts to identify and isolate early embryonic cell progenitors are important to provide tools for elucidating regulatory elements in vasculogenesis and to potentially shed light on vasculogenic and angiogenic mechanisms involved in pathological situations affecting the vascular system (p 4396, 2nd paragraph). **Levenberg** also teaches that unlike the mouse system the lack of experimental cell systems has made it difficult to study developmental processes in the human (p 4391, 1st column) and suggests it would be important to examine the efficiency of embryonic stem cell differentiation into endothelial cells in applications such as tissue engineering of vascular grafts (p 4396, 1st column). **Levenberg** differs from the claimed invention for not teaching exposing the embryonic stem cells to activin A and IGF wherein the cells produce alpha-fetoprotein and albumin.

However, at the time the claimed invention was made, **Benvenisty et al,** teach methods for mapping a pathway of differentiation of a population of embryonic stem cells which includes exposing the cells to Activin A and wherein cells differentiated into muscle-like syncytium (page 7, 2nd column, example 2). **Benvenisty et al,** reports while human embryonic stem cells have been recovered from human embryos produced by in vitro fertilization, the formation of

embryoid bodies from human primates and from humans has been problematic and the formation of embryoid bodies from primates is inconsistent and asynchronous (p 1, 1st column). **Benvenisty et al,** have also suggested it is desirable to have tools to analyze and compare pathways indifferent mammals and to combine those these tools with a methodology that permits the isolation, preservation and cultivation of embryonic stem cells from mammals for transplantation in numerous human pathologies as a component in biomedical engineering (p 1 columns 1-2). As such, **Benvenisty** provides sufficient motivation for one of ordinary skill in the art to apply the three-dimensional cell support system of **Levenberg** exposing the cells to activin A wherein using human embryonic stem cells to analyze and compare pathways indifferent mammals and to combine those these tools with a methodology that permits the isolation, preservation and cultivation of embryonic stem cells from mammals for transplantation in numerous human pathologies as a component in biomedical engineering.

Accordingly, in view of the teachings of **Benvenisty et al,** it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the three dimensional construct of **Levenberg** by use human embryonic stem cells exposed to activin A with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as it was taught by **Levenberg** exposing the cells to activin A wherein using human embryonic stem cells to analyze and compare pathways in different mammals and to combine those these tools with a methodology that permits the isolation, preservation and cultivation of embryonic stem cells from mammals for transplantation in numerous human pathologies as a component in biomedical engineering, in particular as Levenberg suggested it is desirable to have tools to analyze and compare pathways indifferent mammals and to combine those these tools with a methodology that permits the isolation,

preservation and cultivation of embryonic stem cells from mammals for transplantation in numerous human pathologies as a component in biomedical engineering.

Thus, the claimed invention as a whole is clearly prima facie obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

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Art Unit 1632

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